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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,325	ESCARY, JEAN-LOUIS	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-4**, drawn to an isolated polynucleotide comprising SEQ ID NO: 1, classified in class 536, subclass 23.1, for example.

II. Claim **5**, drawn to a method of identifying or amplifying a polynucleotide with the nucleotide sequence SEQ ID NO: 1, classified in class 435, subclass 6, for example.

III. Claims **6-7**, drawn to a method for genotyping a polynucleotide with the nucleotide sequence SEQ ID NO: 1, classified in class 435, subclass 6, for example.

IV. Claims **8-10**, drawn to a method of making a polypeptide including recombinant vector and host cell comprising same, classified in class 435, subclass 69.1, for example.

V. Claims **11-13**, drawn to a polypeptide encoded by the nucleotide sequence SEQ ID NO: 1, classified in class 530, subclass 300, for example.

VI. Claim **14**, drawn to a method for obtaining an immunospecific antibody, classified in class 424, subclass 184.1, for example.

VII. Claim **15**, drawn to an immunospecific antibody, classified in class 530, subclass 387.1, for example.

VIII. Claims **16-17** and **31-32**, drawn to a method for identifying an agent, classification dependent upon agent structure.

IX. Claim **18**, drawn to a method for analyzing the biological characteristics of a subject, classified in class 435, subclass 4, for example.

X. Claim **19**, drawn to a therapeutic agent comprising an *isolated polynucleotide* and recombinant vectors comprising same, classified in class 536, subclass 44, for example.

XI. Claim **19**, drawn to a therapeutic agent comprising an *isolated host cell*, classified in class 424, subclass 93.2, for example.

XII. Claim **19**, drawn to a therapeutic agent comprising an isolated *polypeptide*, classified in class 514, subclass 2, for example.

XIII. Claim **19**, drawn to a therapeutic agent comprising an *antibody*, classified in class 424, subclass 130.1, for example.

XIV. Claim **21**, drawn to a method for preventing or treating an individual with cancers and tumors, classification dependent upon agent structure.

XV. Claim **22**, drawn to a method for preventing or treating an individual with metabolic diseases, classification dependent upon agent structure.

XVI. Claim **23**, drawn to a method for preventing or treating an individual with viral infections, classification dependent upon agent structure.

XVII. Claim **24**, drawn to a method for preventing or treating an individual with diseases of the central nervous system, classification dependent upon agent structure.

XVIII. Claim **25**, drawn to a method for preventing or treating an individual with immunological and auto-immunological related diseases, classification dependent upon agent structure.

XIX. Claim **26**, drawn to a method for preventing or treating an individual, classification dependent upon agent structure.

XX. Claim **27**, drawn to a method for increasing or decreasing the activity in a subject comprising administering an *isolated polynucleotide* and recombinant vectors comprising same, classified in class 536, subclass 44, for example.

XXI. Claim **27**, drawn to a method for increasing or decreasing the activity in a subject comprising administering an *isolated host cell*, classified in class 424, subclass 93.2, for example.

XXII. Claim **27**, drawn to a method for increasing or decreasing the activity in a subject comprising administering an isolated *polypeptide*, classified in class 514, subclass 2, for example.

XXIII. Claim **27**, drawn to a method for increasing or decreasing the activity in a subject comprising administering an *antibody*, classified in class 424, subclass 130.1, for example.

XXIV. Claim **28**, drawn to a method for preventing or treating an individual with a disorder or a disease linked to the presence in the genome of the polynucleotide with the nucleic acid sequence of SEQ ID NO: 1 comprising administering an *isolated polynucleotide* and

recombinant vectors comprising same, classified in class 536, subclass 44, for example.

XXV. Claim **28**, drawn to a method for preventing or treating an individual with a disorder or a disease linked to the presence in the genome of the polynucleotide with the nucleic acid sequence of SEQ ID NO: 1 administering an *isolated host cell*, classified in class 424, subclass 93.2, for example.

XXVI. Claim **28**, drawn to a method for preventing or treating an individual with a disorder or a disease linked to the presence in the genome of the polynucleotide with the nucleic acid sequence of SEQ ID NO: 1 comprising administering an isolated *polypeptide*, classified in class 514, subclass 2, for example.

XXVII. Claim **28**, drawn to a method for preventing or treating an individual with a disorder or a disease linked to the presence in the genome of the polynucleotide with the nucleic acid sequence of SEQ ID NO: 1 comprising administering an *antibody*, classified in class 424, subclass 130.1, for example.

XXVIII. Claim **29**, drawn to a method for determining statistically relevant associations between SNPs, classified in class 435, subclass 6, for example.

XXIX. Claim **30**, drawn to a method for diagnosing or determining a prognosis of a disease or a resistance to a disease comprising detecting a SNP, classified in class 435, subclass 6, for example.

XXX. Claim **33**, drawn to an agent, classification dependent upon structure.

XXXI. Claim **35**, drawn to a method for preventing or treating an individual with cancers and tumors, classification dependent upon agent structure.

XXXII. Claim **36**, drawn to a method for preventing or treating an individual with metabolic diseases, classification dependent upon agent structure.

XXXIII. Claim **37**, drawn to a method for preventing or treating an individual with viral infections, classification dependent upon agent structure.

XXXIV. Claim **38**, drawn to a method for preventing or treating an individual with diseases of the central nervous system, classification dependent upon agent structure.

XXXV. Claim **39**, drawn to a method for preventing or treating an individual with immunological and auto-immunological related diseases, classification dependent upon agent structure.

XXXVI. Claim **40**, drawn to a method for preventing or treating an individual, classification dependent upon agent structure.

2. Claim **19** link(s) inventions X-XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim **19**. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The Examiner notes that restriction is between inventions and not claims. As claim 19 is not a proper Markush as it encompasses several distinct and independent inventions which do not share classifications it has been treated as a linking claim. Claim 19 will be examined on its merits beginning with the election of a single distinct invention.

3. Claim **20** link(s) inventions XIV-XVIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims **21-25**. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or

including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The Examiner notes that restriction is between inventions and not claims.

4. Claim **27** link(s) inventions XX-XXIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim **28**. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The Examiner notes that restriction is between inventions and not claims. As claim 28 is not a proper Markush as it encompasses several distinct and independent inventions which

do not share classifications it has been treated as a linking claim. Claim 28 will be examined on its merits beginning with the election of a single distinct invention.

5. Claim **28** link(s) inventions XXIV-XXVII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim **27**. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The Examiner notes that restriction is between inventions and not claims. As claim 27 is not a proper Markush as it encompasses several distinct and independent inventions which do not share classifications it has been treated as a linking claim. Claim 27 will be examined on its merits beginning with the election of a single distinct invention.

6. Claim **34** link(s) inventions XXXI-XXXV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims **35-39**. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including

all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The Examiner notes that restriction is between inventions and not claims.

7. The inventions are distinct, each from the other because of the following reasons:

8. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, V, VII, X, XI, XII, XIII, and XXX are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

9. The polynucleotide of Invention I is independent and distinct from the polypeptide of Invention V, the antibody of Invention VII, the therapeutic agent of Inventions X-XIII, and the agents of Invention XXX at it can be prepared by process which are materially different, such as by chemical synthesis, or by isolation and purification from natural sources.

10. The polypeptide of Invention V is independent and distinct from the polynucleotide of Invention I, the antibody of Invention VII, the therapeutic agent of Inventions X-XIII, and the agents of Invention XXX at it can be prepared by process which are materially different, such as by chemical synthesis, or by isolation and purification from natural sources.

11. The antibody of Invention VII is independent and distinct from the polynucleotide of Invention I, the polypeptide of Invention V, the therapeutic agents of Inventions X-XIII, and the agent of Invention XXX at it can be prepared by process which are materially different, such as by chemical synthesis, or by isolation and purification from natural sources.

12. The therapeutic agent of Invention X is independent and distinct from the polynucleotide of Invention I, the polypeptide of Invention V, the antibody of Invention VII, the therapeutic agents of Inventions XI-XIII, and the agent of Invention XXX at it can be prepared by process which are materially different, such as by chemical synthesis, or by isolation and purification from natural sources.

13. The therapeutic agent of Invention XI is independent and distinct from the polynucleotide of Invention I, the polypeptide of Invention V, the antibody of Invention VII, the therapeutic agents of Inventions X, XII-XIII, and the agent of Invention XXX at it can be prepared by process which are materially different, such as by chemical synthesis, or by isolation and purification from natural sources.

14. The therapeutic agent of Invention XII is independent and distinct from the polynucleotide of Invention I, the polypeptide of Invention V, the antibody of Invention

VII, the therapeutic agents of Inventions X, XI, XIII, and the agent of Invention XXX at it can be prepared by process which are materially different, such as by chemical synthesis, or by isolation and purification from natural sources.

15. The therapeutic agent of Invention XIII is independent and distinct from the polynucleotide of Invention I, the polypeptide of Invention V, the antibody of Invention VII, the therapeutic agents of Inventions X, XI, XII, and the agent of Invention XXX at it can be prepared by process which are materially different, such as by chemical synthesis, or by isolation and purification from natural sources.

16. The agent of Invention XXX is independent and distinct from the polynucleotide of Invention I, the polypeptide of Invention V, the antibody of Invention VII, the therapeutic agents of Inventions X-XIII at it can be prepared by process which are materially different, such as by chemical synthesis, or by isolation and purification from natural sources.

17. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions II, III, IV, VI, VIII, IX, XIV, XV, XVI, XVII, XVIII, XIX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XIX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV and XXXVI are directed to methods that are distinct both physically and functionally, and are not required one for the other.

18. Invention II requires search and consideration of amplifying a polynucleotide, which is not required by any of the other Inventions.

19. Invention III requires search and consideration of genotyping a polynucleotide, which is not required by any of the other Inventions.

20. Invention IV requires search and consideration of making a polypeptide, which is not required by any of the other Inventions.

21. Invention VI requires search and consideration of making an antibody, which is not required by any of the other Inventions.

22. Invention VIII requires search and consideration of identifying an agent, which is not required by any of the other Inventions.

23. Invention IX requires search and consideration of analyzing the biological characteristics of a subject, which is not required by any of the other Inventions.

24. Invention XIV requires search and consideration of treating cancers using one of the therapeutic agents of Inventions X-XIII, which is not required by any of the other Inventions.

25. Invention XV requires search and consideration of treating metabolic disease using one of the therapeutic agents of Inventions X-XIII, which is not required by any of the other Inventions.

26. Invention XVI requires search and consideration of treating viral infections using one of the therapeutic agents of Inventions X-XIII, which is not required by any of the other Inventions.

27. Invention XVII requires search and consideration of treating central nervous system diseases using one of the therapeutic agents of Inventions X-XIII, which is not required by any of the other Inventions.

28. Invention XVIII requires search and consideration of treating immunological diseases using one of the therapeutic agents of Inventions X-XIII, which is not required by any of the other Inventions.

29. Invention XIX requires search and consideration of healing wounds using one of the therapeutic agents of Inventions X-XIII, which is not required by any of the other Inventions.

30. Invention XX requires search and consideration of administering a polynucleotide to increase or decrease the activity in a subject of a polypeptide, which is not required by any of the other Inventions.

31. Invention XXI requires search and consideration of administering a host cell to increase or decrease the activity in a subject of a polypeptide, which is not required by any of the other Inventions.

32. Invention XXII requires search and consideration of administering a polypeptide to increase or decrease the activity in a subject of a polypeptide, which is not required by any of the other Inventions.

33. Invention XXIII requires search and consideration of administering a antibody to increase or decrease the activity in a subject of a polypeptide, which is not required by any of the other Inventions.

34. Invention XXIV requires search and consideration of preventing or treating an individual with a disorder or a disease linked to the presence in the genome comprising administering a polynucleotide, which is not required by any of the other Inventions.

35. Invention XXV requires search and consideration of preventing or treating an individual with a disorder or a disease linked to the presence in the genome comprising administering a host cell, which is not required by any of the other Inventions.

36. Invention XXVI requires search and consideration of preventing or treating an individual with a disorder or a disease linked to the presence in the genome comprising administering a polypeptide, which is not required by any of the other Inventions.

37. Invention XXVII requires search and consideration of preventing or treating an individual with a disorder or a disease linked to the presence in the genome comprising administering an antibody, which is not required by any of the other Inventions.

38. Invention XXVIII requires search and consideration of determining statistically relevant associations between SNPs, which is not required by any of the other Inventions.

39. Invention XXIX requires search and consideration of diagnosing or determining a prognosis of a disease or a resistance to a disease comprising detecting a SNP, which is not required by any of the other Inventions.

40. Invention XXXI requires search and consideration of treating cancers using one therapeutic agent of Inventions XXX, which is not required by any of the other Inventions.

41. Invention XXXII requires search and consideration of treating metabolic diseases using the therapeutic agent of Inventions XXX, which is not required by any of the other Inventions.

42. Invention XXXIII requires search and consideration of treating viral infections using one therapeutic agent of Inventions XXX, which is not required by any of the other Inventions.

43. Invention XXXIV requires search and consideration of treating central nervous system diseases using the therapeutic agent of Inventions XXX, which is not required by any of the other Inventions.

44. Invention XXXV requires search and consideration of treating immunological diseases using the therapeutic agent of Inventions XXX, which is not required by any of the other Inventions.

45. Invention XXXVI requires search and consideration of wound healing using one of the therapeutic agent of Inventions XXX, which is not required by any of the other Inventions.

46. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polynucleotide can be made through materially different methods such as chemical synthesis or purification from natural sources.

47. Inventions I and each of Inventions III, IV, VIII, IX, XIV, XV, XVI, XVII, XVIII, XIX, XX, XXIV, XXVIII, and XXIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide can be used in materially different method such as making probes or screening for binding partners (i.e. yeast-two-hybrid screening assay).

48. Inventions I and each of VI, XXI, XXII, XXIII, XXV, XXVI, XXVII, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and each of VI, XXI, XXII, XXIII, XXV, XXVI, XXVII, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI, XXI, XXII, XXIII, XXV, XXVI, XXVII, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI do not recite the use or production of the polynucleotide of Invention I.

49. Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case the polynucleotide can be made through materially different methods such as chemical synthesis or purification from natural sources.

50. Inventions V and each of VI, VIII, IX, XIV, XV, XVI, XVII, XVIII, XIX, XXII, and XXVI Inventions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in materially different method such as making probes or screening for binding partners (i.e. yeast-two-hybrid screening assay).

51. Inventions V and each of II, III, XX, XXI, XXIII, XXIV, XXV, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions V and each of II, III, XX, XXI, XXIII, XXIV, XXV, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, III, XX, XXI, XXIII, XXIV, XXV, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI do not recite the use or production of the polypeptide of Invention V.

52. Inventions VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody can be made through materially different methods such as chemical synthesis or purification from natural sources.

53. Inventions VII and each of XIV, XV, XVI, XVII, XVIII, XIX, XXIII, and XXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in materially different method such as making probes or screening for binding partners (i.e. yeast-two-hybrid screening assay).

54. Inventions VII and each of II, III, IV, VIII, IX, XX, XXI, XXII, XXIV, XXV, XXVI, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and each of II, III, IV, VIII, IX, XX, XXI, XXII, XXIV, XXV, XXVI, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed

methods of Inventions II, III, IV, VIII, IX, XX, XXI, XXII, XXIV, XXV, XXVI, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI do not recite the use or production of the antibody of Invention VII.

55. Inventions X and each of XIV, XV, XVI, XVII, XVIII, and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the therapeutic polynucleotide can be used in materially different method such as making probes or screening for binding partners (i.e. yeast-two-hybrid screening assay).

56. Inventions X and each of II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions X and each of II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI do not recite the use or production of the therapeutic polynucleotide of Invention X.

57. Inventions XI and each of XIV, XV, XVI, XVII, XVIII, and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the therapeutic host cell can be used in materially different method such as making polypeptides.

58. Inventions XI and each of II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XI and each of II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI do not recite the use or production of the therapeutic host cell of Invention XI.

59. Inventions XII and each of XIV, XV, XVI, XVII, XVIII, and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the therapeutic polypeptide can be used in materially different method such as making probes or screening for binding partners (i.e. yeast-two-hybrid screening assay).

60. Inventions XII and each of II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XII and each of II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI do not recite the use or production of the therapeutic polypeptide of Invention XII.

61. Inventions XIII and each of XIV, XV, XVI, XVII, XVIII, and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the therapeutic antibody can be used in materially different method such as making probes or screening for binding partners (i.e. yeast-two-hybrid screening assay).

62. Inventions XIII and each of II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XIII and each of II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, III, IV, VI, VIII, IX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI do not recite the use or production of the therapeutic antibody of Invention XIII.

63. Inventions XXX and each of XXXI, XXXII, XXXIII, XXXIV, XXXV, and XXXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agent can be used in materially different method such as screening for binding partners (i.e. yeast-two-hybrid screening assay).

64. Inventions XXX and each of II, III, IV, VI, VIII, IX, XIV, XV, XVI, XVII, XVIII, XIX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, and XXIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different

effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XXX and each of II, III, IV, VI, VIII, IX, XIV, XV, XVI, XVII, XVIII, XIX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, and XXIX are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, III, IV, VI, VIII, IX, XIV, XV, XVI, XVII, XVIII, XIX, XX, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, and XXIX do not recite the use or production of the agent of Invention XXX.

65. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Metastasizing renal carcinomas

b. Melanomas

c. Follicular lymphomas

d. Cutaneous T cell lymphoma

e. Hairy-cell leukemia

f. Chronic lymphocytic leukemia

g. Chronic myeloid leukemia

h. Liver cancer

i. Neck cancer

j. Head cancer

k. Kidney cancer

l. Multiple myeloma

m. Carcinoid Tumor

n. Kaposi's sarcoma tumors due to AIDS

66. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims **21** and **35** are generic.

67. If applicant selects Invention XIV or XXXI, one species from the cancers/tumors group must be chosen to be fully responsive.

68. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

69. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

70. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

71. This application contains claims directed to the following patentably distinct species of the claimed invention:

o. Chronic hepatitis B

p. Chronic hepatitis C

q. HIV/AIDS

r. Infectious pneumonias

s. Venereal diseases

72. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims **23** and **37** are generic.

73. If applicant selects Invention XVI or XXXIII, one species from the infectious diseases group must be chosen to be fully responsive.

74. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

75. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

76. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

77. This application contains claims directed to the following patentably distinct species of the claimed invention:

t. Alzheimer's disease

u. Parkinson's disease

v. Schizophrenia

w. Depression

78. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims **24** and **38** are generic.

79. If applicant selects Invention XVII or XXXIV, one species from the central nervous system disease group must be chosen to be fully responsive.

80. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

81. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

82. This application contains claims directed to the following patentably distinct species of the claimed invention:

x. Tissue rejection

y. Organ grafts

z. Allergies

aa. Asthma

bb. Psoriasis

cc. Rheumatoid arthritis

dd. Multiple sclerosis

ee. Crohn's disease

ff. Ulcerative colitis

83. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims **25** and **39** are generic.

84. If applicant selects Invention XVIII or XXXV, one species from the immunological and auto-immunological disease group must be chosen to be fully responsive.

85. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

86. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

87. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

88. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain

dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

89. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

90. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

91. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

92. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda

Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 10/04

Brenda Brumback

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